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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,217	03/04/2002	Yong Yao	053735-5004-01	2158
9629	7590	06/13/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP			ULM, JOHN D	
1111 PENNSYLVANIA AVENUE NW			ART UNIT	
WASHINGTON, DC 20004			PAPER NUMBER	
			1646	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
10/087,217	YAO ET AL.	
Examiner	Art Unit	
John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-24, 26, 28-41, 43-45, 47, 49-62, 64-67, 69, 71 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24, 26, 28-41, 43-45, 47, 49-62, 64-67, 69, 71 and 73-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are pending in the instant application. Claims 22, 26, 43, 47, 49, 64 and 69 have been amended and claims 42 and 63 have been canceled as requested by Applicant in the correspondence filed 25 May of 2005.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 May of 2005 has been entered.

5) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A claim that omits a step or element that is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant claims are directed to a "method of detecting activity of a G protein-coupled receptor" by indirectly measuring the activity of a mutant GNC channel in a recombinant cell. As indicated in section 5 of the previous office action, because most, if not all,

Art Unit: 1646

mammalian cells express a variety of endogenous G protein-coupled receptors an artisan can not attribute a measured channel activity to a specific G protein-coupled receptor, to the exclusion of all of the other G protein-coupled receptors expressed by a test cell, in the absence of a comparative step that employs a cell that is otherwise identical to the test cell except for the absence of receptor protein of interest. These claims are not enabled because the instant specification does not provide the guidance needed to practice the claimed method without employing such a comparative step. The position that most, if not all, mammalian cells express a variety of endogenous G protein-coupled receptors is supported by the text in line 1 on page 3 of the instant specification, which states that "GPCRs are found in all tissues". Applicant urges that "it is unnecessary to include such a step because the use of controls, such as the use of a negative control referred to by the Examiner, was well known by those of ordinary skill in the art at the time the present application was filed" and that "the use of a negative control for a G coupled protein receptor was known in the art". Whereas the use of such controls is certainly well known in the art, the instant rejection is based upon the fact that the instant claims encompass a process that omits this critical element whereas the instant specification does not provide the guidance needed to practice that process without that element.

6) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 also lack enablement because the instant specification does not provide the guidance needed to practice the claimed method with a membrane potential dye that does not produce a fluorescent signal in response to cell depolarization. Nothing in the

Art Unit: 1646

instant specification or the art of record indicates that all “membrane potential dyes” or “voltage sensitive dyes”, as described on page 16 of the instant specification, produce a fluorescent signal in response to cell depolarization. Whereas the instant claims encompass a method that employs a membrane potential dye that does not produce a fluorescent signal in response to cell depolarization, the instant specification does not enable a practitioner to measure a a fluorescent signal from such a dye.

7) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) Claims 22 to 24, 26, 28 to 41, 43 to 45, 47, 49 to 62, 64 to 67, 69, 71 and 73 to 82 are vague and indefinite because there is no antecedent basis for “detectable fluorescence signals from the dye”. These claims are not limited to a dye that produces “fluorescence signals”.

7.2) Claims 39, 60 and 82 are confusing because the relationship between the “promiscuous G protein” and the “G protein-coupled receptor” recited therein is not specified.

7.3) Claims 41 and 62 are confusing because it is unclear if the limitation “a dye” is referring to the “at least one membrane potential dye” or an additional dye of unspecified function.


8) Applicant's arguments filed 25 May of 2005 have been fully considered but they are not persuasive for those reasons given above.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800